

| | | | |
|-------------------------------|-----------------|--------------|--|
| Notice of Allowability | Application No. | Applicant(s) | |
| | 09/084,691 | BUKH ET AL. | |
| | Examiner | Art Unit | |
| | Zachariah Lucas | 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment of June 29, 2005, and the interview of July 18, 2005.
2. ☒ The allowed claim(s) is/are 4,5, 11-16, 19, and 32-44, and 46.
3. ☒ The drawings filed on 26 May 1998 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>7/18/05</u> 7-19-05 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____ |
|---|---|

Art Unit: 1648

DETAILED ACTION

1. Currently, claims 4, 5, 11-16, 19, 32-44, and 46 are pending in the application. These claims are allowed as presented in the amendment of June 29, 2005, or as amended below.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Nancy W. Vensco on July 18, 2005.

The application has been amended as follows:

Claim 32 has been amended to read as follows:

32. An isolated genotype-specific peptide comprising an amino acid sequence of at least 8 contiguous amino acids from SEQ ID NO: 206, said peptide having at least one of the following residues: Q72, H75, H106, A149, and I158; and wherein genotype-specific is defined as belonging to the single genotype 6a (type 6) of HCV.

Claim 33 has been amended to replace the phrase "a single genotype of HCV" in lines 1 to 2 of the claim with the phrase - - the single genotype 6a (type 6) of HCV- -.

Art Unit: 1648

Claim 38 has been amended to replace the phrase "at least 8 amino acids" in line 2 of the claim with the phrase - - at least 8 consecutive amino acids- -,

and to replace the term "Figure 7J" in line 4 of the claim with the term - - Figure 7K- -.

The amendments to claim 32 were made to avoid possible rejections of the claim over the teachings of Simmonds et al., J Gen Virol 74: 661-668. The teachings of the reference caused two concerns necessitating the amendments. First, the reference taught a peptide (page 665, Figure 3 (b), HCV EG-21) falling within the scope of claim 32 in that the peptide included a residue indicated by Figure 7K (providing substantially the same teachings as Figure 7J) as being genotype-specific to HCV type 6a. I.e., the indicated sequence of Simmonds included a threonine at position 20 (T20), which according to Figure 7K would be considered a genotype specific residue to type 6a.

The second problem created by the teachings of Simmonds was that the indicated sequence (comprising the T20 residue) disclosed in the reference was disclosed as a HCV type 4 sequence, whereas the claim indicated that a peptide comprising this sequence was specific to type 6. Because Simmonds indicated that this residue was not in fact specific to type 6, the reference created a potential enablement rejection.

Claim 32, and the genotype-specific claims which depend therefrom, have now been amended such that they are limited to peptides comprising at least 8 consecutive residues of SEQ ID NO: 206, wherein the sequences of these residues comprise at least one of the following residues of SEQ ID NO: 206: Q72, H75, H106, A149, and I158. As can be seen from Figure 7K, these residues each represent a genotype-specific residue to HCV type 6a. Thus, the amendment

Art Unit: 1648

both excludes the Simmonds peptide (which does not share any of these five residues), and overcomes its teachings regarding the genotype specificity of the T20 residue by specifically indicating which residues in the sequence define a genotype-specific sequence within SEQ ID NO: 206.

The amendment of 33 is made to clarify that the peptides of claim 32 are being used in the method of claim 33 to identify antibodies specific to HCV type 6a, the genotype represented by the peptides of claim 32.

The amendment of claim 38 is made to clarify that the “at least 8 amino acids” must be consecutively placed within SEQ ID NO: 206, and to refer to Figure 7K, which appears more easily studied than Figure 7J, while providing the same information with reference to SEQ ID NO: 206. For the purposes of defining an universally conserved peptide according to claim 38, such peptides are identified as peptides consisting of a sequence or at least 8 residues in length with only dashes in the line corresponding to SEQ ID NO: 206, and only capital letters in the sequence in the top line of the Figure (the consensus sequence).

Claim Objections

3. **(Prior Objection- Withdrawn)** Claims 4 and 5 were objected to because of the following informalities: It was suggested that the claims be amended to read on a protein encoded by - - the- - gene sequence SEQ ID NO: 154, or having - -the- - amino acid sequence of SEQ ID NO: 206 to clarify that the claims read on the full length protein. In view of the amendments to the claim, the objection is withdrawn.

Claim Rejections - 35 USC § 102

4. **(Prior Rejection- Withdrawn)** Claims 32-44, 46, and 59 were rejected under 35 U.S.C. 102(b) as being anticipated by DeLeyes et al. (EP 0 489 968 A). In view of the limitation of the universally conserved peptides to sequences consisting of universally conserved domains of SEQ ID NO: 206 (as defined by Figure 7K- those domains of at least residues comprising only of letters in capital case in the sequence provided in the Figure), or to genotype-specific peptides comprising a contiguous sequence of SEQ ID NO: 206 having at least one of the residues Q72, H75, H106, A149, and I158, the rejection is withdrawn.
5. **(Prior Rejection- Withdrawn)** Claims 38-42, 44, 46, and 59 were rejected under 35 U.S.C. 102(b) as being anticipated by Ferroni et al., J Clin Microbiol 31(6): 1586-91. In view of the limitation of the universally conserved peptides to sequences consisting of universally conserved domains of SEQ ID NO: 206 (as defined by Figure 7K- those domains of at least residues comprising only of letters in capital case in the sequence provided in the Figure), or to genotype-specific peptides comprising a contiguous sequence of SEQ ID NO: 206 having at least one of the residues Q72, H75, H106, A149, and I158, the rejection is withdrawn.
6. **(Prior Rejection- Withdrawn)** Claims 32, 37, 38, 43, 44, and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Chien et al. (U.S. Patent 6,054,264). In view of the amendments to the claims as described above, the rejection is withdrawn.
7. **(Prior Rejection-Withdrawn)** Claims 32, 37, 38, 43, 44, and 46 were rejected under 35 U.S.C. 102(e) as being anticipated by Miyamura et al. (U.S. 5,856,437). In view of the amendments to the claims as described above, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

8. **(Prior Rejection-Withdrawn)** Claims 33-36 and 39-42 43 were rejected under 35 U.S.C. 103(a) as being unpatentable over Chien as applied to claims 32, 37, 38, 43, 44, and 46 above, and as applied in combination with Li in the prior action. In view of the amendments to the claims as described above, the rejection is withdrawn.

9. **(Prior Rejection-Withdrawn)** Claims 33-36 and 39-42 43 were rejected under 35 U.S.C. 103(a) as being unpatentable over Miyamura as applied to claims 32, 37, 38, 43, 44, and 46 above. In view of the amendments to the claims as described above, the rejection is withdrawn.

Conclusion

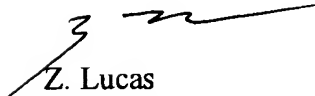
10. All claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas
Patent Examiner



7/25/05
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600